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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/033,543      | 12/27/2001  | Joseph H. Contiliano | ETH-1615            | 7364             |

7590

10/16/2003

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EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/033,543

Applicant(s)

CONTILIANO ET AL

Examiner

Pedro Philogene

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2-6,8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhling et al. (5,169,400) in view of Massa (5,030,048).

With respect to claim 1, Muhling et al disclose a medical screw and driver system comprising: an elongated screw (1) having external threads (3) and an internal bore (5) extending through the screw at least a portion of the length of the screw, the screw being at least partially formed from a bio-absorbable material; as set forth in column 3, line 68, column 4, lines 1-5; an elongated driver (7,8) having a non-circular cross-section shape approximating the cross-sectional shape of the bore, as set forth in column 3, lines 65-68, column 4, lines 24-40, the driver insertable into the bore and being matingly received therein to transfer rotational motion of the driver to the screw, the bore exhibiting a closely fitting-fit relative to the driver, as set forth in column 3, lines 25-50, column 4, lines 32-40.

Although Muhling discloses a fitting relative to the driver, it is noted that muling did not teach of a shrink-fit relative to the driver, and the driver is removable from the bore; as claimed by applicant. However, in a similar art, Massa evidences the use of a shrink-fit relative to the to the driver, and the driver is removable from the bore to provide a device that is reliable and avoids frequent breakdowns or failures.

Therefore, given the teaching of Massa, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the shrink-fit method and the removable driver as taught by Massa in the device of Muhling to provide a device that is reliable and avoids frequent breakdowns or failures.

With respect to claims 2-6,9, Muhling et al discloses all the limitations, as set forth in column 4, lines 1-5,19-23,30-40; column 2, lines 39-47 and as best seen in FIGS: 1-12.

With respect to claim 8, it noted that the above combination of references discloses all the limitations, except for a ratio of an 15/85 blend of TCP/PLA, as claimed by applicant. However, applicant fails to establish the criticality of such a ratio. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach the optimum range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum range or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 7,10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhling et al. (5,169,400) in view of Massa (5,030,048) in view of Tunc (5,827,287).

With respect to claims 7,8, it is noted that the above combination of references did not teach of a screw having an additive to the composition thereof selected from the group consisting of bio-absorbable glass, as claimed by applicant. However, in a similar art, Tunc evidences the use of bio-absorbable glass to cause nucleation and to form a self-supporting member.

Therefore, given the teaching of Tunc, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the additive of Tunc in the composition of Muhling/Massa to cause nucleation and to form a self-supporting member.

With respect to claims 10-20, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above. Furthermore the combination of references taught of changes in temperature, bonding and melting; however, they fail to teach of a temperature between 70 and 100 degree Celsius from four hours to about eight hours; as claimed by applicant. However, applicant fails to establish the criticality of such temperatures and hours, and the examiner believes that any temperatures and hours could have been used, since the device would have performed equally as well with any given temperatures and hours.

### ***Response to Amendment***

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

|           |         |               |
|-----------|---------|---------------|
| 6,096,060 | 08-2000 | Fitts et al.  |
| 6,565,291 | 05-2003 | Harpaz et al. |

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

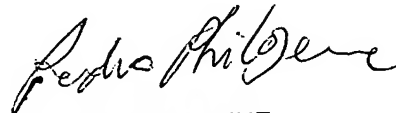
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene  
October 14, 2003



PEDRO PHILOGENE  
PRIMARY EXAMINER